

**Remarks**

Claims 1, 6, 9, 14-20, and 27-30 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Young (USP 5,677,279) in view of Iovanna (USP 5,436,169), Valter (Derwent Acc 1979-G6671B and/or SU 628925A, abstract), Jorgensen (USP 4,370,317), and Haddad ("The Use of a Low Fat Diet in the Treatment of Acute Pancreatitis," *American Journal of Gastroenterology*, (Sept. 2000), Vol. 95, No. 9, pp. 2479).

This rejection is respectfully traversed. Young discloses that amylin and amylin agonists can be used for analgesia in mammals (Col. 5, lines 55-61). Iovanna discloses that acute abdominal pain is one indicia of diagnosis of pancreatitis. Nevertheless, the present invention is not directed towards treating pain. Rather, the present claims are directed towards the treatment of pancreatitis by the administration of amylin or an amylin analog.

Before analyzing the rationale of the rejection, it is important to consider the Declaration submitted herewith of Dr. Steve Chen, M.D.. As Dr. Chen states at paragraphs 3-4 of his Declaration, there are two major categories of pancreatitis. The first type of pancreatitis is "acute pancreatitis," which occurs suddenly when digestive enzymes produced in the pancreas remain there and become active, irritating and inflaming pancreatic tissue (normally digestive enzymes are transported to the duodenum, and become active there). The other type of pancreatitis is "chronic pancreatitis," which differs from acute pancreatitis in that the inflammation happens over a period of years and can cause permanent damage to the pancreas. Chronic pancreatitis is usually less obvious than the acute form, and in its early stages can be difficult to recognize. Some people with chronic pancreatitis have no pain. Other people have intermittent periods of mild to moderate abdominal pain. As inflammation persists, it slowly destroys the pancreas. Unfortunately, the pain accompanying chronic pancreatitis usually lessens as the condition progresses and worsens, apparently because the pancreas is no longer making digestive enzymes. As noted by Dr. Chen, chronic pancreatitis often causes no pain or other symptoms and may be discovered by accident during the course of investigation of symptoms not related to pancreatitis (e.g. calcification of the pancreas may be seen on an x-ray of the abdomen performed for other reasons).

It is noted that the rejection appears to allege that by administering amylin as an analgesic to a patient suffering from pain, one is inherently treating pancreatitis. It is first noted that the rejection is made under 35 U.S.C. § 103(a), and inherency is a concept applicable only in the context of anticipation, not obviousness. The rejection uses the word “intrinsically” but this appears to be a mere substitute for “inherently” (Office Action mailed 1/30/09, p. 4, lines 12-14) and Applicants submit that the mere substitution of “intrinsic” for “inherent” does not change the rationale of the rejection from one of anticipatory inherency. Such a concept of inherency is necessarily contained in the rejection because Young provides no disclosure or suggestion to utilize amylin for the treatment of pancreatitis, or that its administration causes a lowering of pancreatic enzymes. But such a rejection based in inherency is out of place in an obviousness rejection. The Federal Circuit has made clear that “a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.” *In re Rijckaert*, 9 F.3d 1531; 28 USPQ2d 1955 (Fed. Cir. 1993). Thus, without the requisite disclosures, suggestions or rational underpinning, no prima facie case of obviousness has been made.

As noted in the Declaration of Dr. Chen, pain does not always accompany pancreatitis. The treatment of pancreatitis is a distinct issue from treating pain, even when treating pain caused by pancreatitis. No prima facie case of obviousness has been made because neither reference, nor any combination thereof, discloses or suggests the treatment of pancreatitis with amylin or an amylin analog. Nor does either reference disclose or suggest that the administration of amylin to a person suffering from pancreatitis causes a beneficial reduction or inhibition in the level of inflammation, enzymatic activity or enzymatic secretion in pancreatic cells. If the rejection is arguing that such effects are inherent in the administration, the use of the concept of inherency is misplaced and legally inappropriate in an obviousness rejection, as the Federal Circuit has stated that a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. *Id.* Even using a legally inappropriate inherency rationale, the rejection would still fail because the Federal Circuit has made clear that inherency “may not be established by probabilities or possibilities. *In re Robertson*, 160 F.3d 743; 49 USPQ2d 1949 (Fed. Cir. 1999). And “the mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation...” *Electro Medical Systems, S.A. v.*

*Cooper Life Sciences, Inc.*, 34 F.3d 1048; 32 USPQ2d 1017 (Fed. Cir. 1994). Rather, it is necessary to prove the feature is “necessarily present in the disclosure, and that it would be so recognized by persons of ordinary skill.” *Id.* In the present case pain does not “necessarily” accompany pancreatitis, and thus even using an inappropriately applied inherency analysis, the rejection still fails. The Federal Circuit has also affirmed a finding that “in order for a claim to be inherent in the prior art it is not sufficient that a person following the disclosure sometimes obtain the result set forth in the claim, it must invariably happen.” (emphasis added) *Glaxo Inc. v. Novopharm Ltd.*, 830 F. Supp. 871; 29 USPQ2d 1126 (E.D. N.C. 1993), *aff’d*, 52 F.3d 1043; 34 USPQ2d 1565 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 988 (1995). Inherency may not be established by probabilities or possibilities. There mere fact that a certain thing may result from a given set of circumstances is not sufficient. Since pain does not invariably accompany pancreatitis, the treatment of pain with amylin does not inherently involve the treatment of pancreatitis with amylin.

To make a proper determination under 35 U.S.C. 103(a), the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. Impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP 2142.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reasons why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398; 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the

legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). MPEP 2142.

The claims are not rendered obvious by the stated combination for yet another reason, which is that administration of amylin to a patient suffering from pancreatitis provides the unexpected benefit of simultaneously reducing pancreatic enzyme levels associated with the disease (specification, paragraph 73). This benefit is not disclosed or suggested by any of the cited references or combination thereof.

Furthermore, as noted in the Declaration of Dr. Chen, pain does not always accompany pancreatitis, so no motivation is present to treat the pancreatitis by administering amylin. As explained by Dr. Chen in his Declaration at paragraph 5, pain and pancreatitis do not always overlap. When pancreatitis does cause pain, the patient would administer a pain killer during times necessary to relieve the pain, and discontinue administration when pain ceases. Thus, a motivation to treat pain with amylin is not a motivation to treat pancreatitis with amylin. Furthermore, Dr. Chen also explains that the starting point for treatment of pain is oral therapy, not with an injectable such as amylin (Declaration of Dr. Chen, paragraph 6). For this reason as well no motivation is present to treat the pain of pancreatitis with amylin.

For all of these reasons, the claims are not obvious over the cited combination.

**Closing**

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 0101-UTL-0. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: June 30, 2009

Respectfully submitted,



Richard San Pietro  
Reg. No. 45,071

Amylin Pharmaceuticals, Inc.  
9360 Towne Centre Drive  
San Diego, California 92121  
Phone (858) 754-4981  
Facsimile (858) 552-1936